ATTACHMENT 1

sybron dental specialties

K090458

Section III - 510(k) Summary of Safety and Effectiveness

MAY 28 2009

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz - Contact Person

Date Summary Prepared: February 2009

Device Name:

- Trade Name – ***DEXIS Sensor***
- Common Name – Digital X-ray
- Classification Name – Extraoral source x-ray system, per 21 CFR § 872.1800

Devices for Which Substantial Equivalence is Claimed:

- Schick Technologies, *CDR (K072134)*
- Suni Medical Imaging, Inc., *SuniRay II Digital Radiographic System (K070219)*

Device Description:

The DEXIS sensor is an indirect converting x-ray detector, e.g. incident x-rays are converted by a scintillating material into (visible) light, this light is coupled optically to a light detection imager based on CMOS technology.

The design of the sensor assembly supports the automatic detection of the incident x-rays to generate digital images for dental intra-oral applications.

The DEXIS sensor supports USB 2.0 and USB 1.1 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver.

Intended Use of the Device:

The DEXIS sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.

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Substantial Equivalence:

Descriptive Information	DEXIS Sensor	CDR (K072134)	SuniRay II Digital Radiographic System (K070219)
Indications for Use	The DEXIS sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.	The computed oral radiology system is intended for intra-oral x-ray examinations and indicated for dental patients. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.	The SuniRay II Digital Radiography System is used to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.
Number of Sensors	1	3	2
Sensor Size (mm)	30 x 39	31 x 22 37 x 24 43 x 30	39.5 x 26 43.5 x 31.5
Technology	CMOS	Same	Same
Interface to PC	USB	Same	Same
Dynamic Range	16,384:1	4096:1	4096:1
Sensor Cable Length (m)	2.8	2	1

Conclusion: The *DEXIS Sensor* is substantially equivalent to other legally marketed devices in the United States. The *DEXIS Sensor* is substantially equivalent in intended use and technical characteristics to the *CDR* marketed by Schick Technologies, Inc. and *SuniRay II Digital Radiographic System* marketed by Suni Medical Imaging, Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2009

DEXIS, LLC
% Ms. Claudia Ortiz
Compliance Director, Regulatory Affairs & Quality Assurance
Sybron Dental Specialties, Inc.
1717 West Collins Drive
ORANGE CA 92656

Re: K090458
Trade/Device Name: DEXIS Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: May 8, 2009
Received: May 11, 2009

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

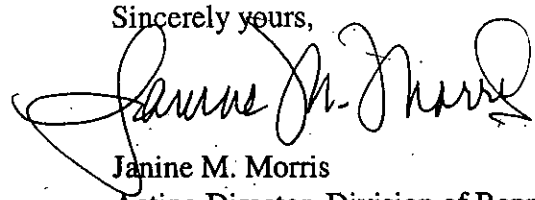
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090458

Device Name: DEXIS Sensor

Indications for Use:

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090458